

REMARKS

Reconsideration is requested.

Claims 36-78 are pending. Claims 42 and 43 have been withdrawn from consideration. Claims 36-41 and 44-78 are under active consideration.

Claims 36-38 have been amended to clarify that the reduced antigen is contained on a dry solid support. Support for the amendments may be found, for example, in Examples 9 and 10 of the specification. No new matter has been added. Basis for the amendments to claims 44-49 may be found, for example, at page 3, lines 20-22 of the specification. Support for the amendments to claim 76 may be found, for example, at page 4, lines 19-22, of the specification. Support for the amendments to claim 77 may be found, for example, at page 3, lines 5-16, of the specification. Support for the amendments to claim 78 may be found, for example, at page 2, line 29 to page 3, line 1, of the specification. No new matter has been added. The amendments do not raise new issues requiring further search and/or consideration. The amendments at least partially obviate the outstanding rejections, as detailed below. Entry of the amendments will therefore, at a minimum, place the application in better form for appeal. Entry of the amendments is requested.

To the extent not obviated by the above amendments, the Section 112, first paragraph, rejection of claims 44-49 stated on page 3 of the Office Action dated June 17, 2003 (Paper No. 16), is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following.

Claims 44-49 have been amended to further indicate that the "part thereof" must include at least one epitope, to clarify that the claims do not read on a single amino

acid, as apparently interpreted by the Examiner. As for the Examiner's apparent confusion relating to the amino acid number recited in the claims, the applicants respectfully submit that one of ordinary skill in the art would not experience such confusion. The Examiner is urged to appreciate in this regard that the numbering of the amino acids of the claims are the same as the numbering of the amino acids in the Seidel (U.S. Patent No. 6,036,579) and Leroux-Roels (WO 95/12677) references cited by the Examiner. One of ordinary skill in the art will appreciate the metes and bounds of the claimed invention. Withdrawal of the Section 112, first paragraph, rejection of claims 44-49 is requested.

The Section 102 rejection of claims 36-41, 50-77 and 78 over Seidel is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

At best, Seidel only provides a reducing agent in contact with an NS3 antigen in the presence of the HCV antibody-containing test sample to which the reducing agent was previously added. That is, Seidel teaches, at best, a combination of a reducing agent and NS3 antigen only in the presence of a an HCV antibody-containing sample. Seidel fails therefore to teach each and every aspect of the presently claimed invention. The reducing agent of Seidel is believed to have been added to the HCV antibody-containing sample in, for example, Example 5 of Seidel, which is then added to the antigen containing solid phase. Any reduced antigen is only produced by Seidel in the presence of the HCV antibody-containing sample, to the extent there is any reducing agent remaining in the sample. Column 4, lines 40-55 of Seidel is believed to support

this conclusion as Seidel merely indicates that "the immunological test can be carried out under mild reducing conditions..." (see, column 4, lines 48-50 of Seidel).

In contrast to Seidel however, the present applicants have discovered that a reduced NS3 protein antigen may be provided as a part of the kit, reducing the requirement for addition of additional reagents, such as reducing agents.

The claims, as amended, are submitted to be patentable over Seidel and entry of the amendments and withdrawal of the Section 102 rejection based on the same are requested.

The Section 102 rejection of claims 36-41 and 50-77 over Figard (U.S. Patent No. 5,616,460), is traversed. Reconsideration and withdrawal of the Section 102 rejection are requested in view of the above amendments and following distinguishing comments.

The applicants submit that Figard (U.S. 5,616,460) discloses, at best, a kit wherein an antigen, reducing agent and support (i.e., microparticles, such as polystyrene microparticles) are contained in the solution buffer of Figard, preferably with an antioxidant, such as ethylene glycol. See, column 4, lines 53-67 (ethylene glycol), column 4, lines 33-52 (reducing agent), column 6, lines 40-54 (solution reaction, and specifically, column 4, lines 40-41 ("... composition of the invention [i.e., Figard] is useful as a diluent of assay components." (emphasis added))), and column 7, lines 43-67 (polystyrene microparticles), of Figard. Figard does not teach or suggest the presently claimed kit wherein reduced antigen is provided on a dry solid support, prior to assay reaction or interaction. Withdrawal of the Section 102 rejection of claims 36-41 and 50-77 over Figard is requested.

The Section 102 rejection of claims 39 and 44-49 over Leroux-Roels (WO 95/12677) is traversed. Reconsideration and withdrawal of the rejection are requested in view of the following distinguishing comments.

The Examiner is understood to be asserting that SEQ ID NO:18 of the present invention is anticipated by Leroux-Roels (WO 95/12677). It is noted that NS3 sequence in Leroux-Roels (WO 95/12677) which may correspond to (i.e. and not be identical to) SEQ ID NO:18 of the present invention, as well as fragments thereof, are disclosed as peptides having T-cell stimulating properties. Leroux-Roels (WO 95/12677) do not disclose, teach or suggest however a solid support coated with a reduced NS3 antigen, as required by the presently claimed invention. The Examiner is requested to indicate, with particularity, where the cited art teaches or suggests the presently claimed invention. Leroux-Roels fails therefore to teach each and every aspect of the presently claimed invention and the Section 102 rejection based on the same should be withdrawn.

The Section 112, second paragraph, rejection of claims 76 and 77 is obviated by the above amendments. Entry of the above and withdrawal of the Section 112, second paragraph, rejection are requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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